

Approved for use through 3/31/2007. OMB 0651-0021 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER PT2116001

U.S. APPLIOTION HOSEL CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/CA2004/001986 November 18, 2004 November 20, 2003 TITLE OF INVENTION Cycloalkyl Derivatives of 3-Hydroxy-4-Pyridinones APPLICANT(S) FOR DO/EO/US Tim Fat Tam, Michael Spino, Wanren Li, Yingsheng Wang, Yanging Zhao and Birenkumar Hasmukhbhai Shah Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. XI This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). 5. X A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. X An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98 12. X An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1,821-1,825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the Inis objection or information is required by 37 CFR 1.414 and 1.4911.4922. The information is required to obtain or retain a benefit by the public, which is to like (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete your including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case, Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. Page 1 of 3

IAP12 Rec'd PCT/PTD 1 9 MAY 2006

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

CATION NO. (if known see 37 CED 1.5)

U.S. APPLICATION NO. (if known, seg 37 CFR 1.5)		INTERNATIONAL APPLICATION NO. PCT/CA2004/001986		ATTORNEY'S DOCKET NUMBER		
1977	000	1 C1/ CR2004/	01360	PT2116001		
20. Other items or	information:					
The following fees have been submitted			CALCULATIONS	PTO USE ONLY		
21. Rasic national	al fee (37 CFR 1.492(a))		\$300	\$ 300.00		
If the written opinion prep by IPEA/US indic	fee (37 CFR 1.492(c)) ared by ISA/US or the internates all claims satisfy provision	\$ 200.00				
If the written opinion of the IPEAUS indicate Search fee (37 CFR 1.44 International Search Republicational Search Republicational Search Republicational Search Republicational Search Republicational Search Republication	37 CFR 1.492(b)) e ISA/US or the International s all claims satisfy provisions 5(a)(2)) has been paid on the rching Authority ort prepared by an ISA other inicated to the US by the IB	\$ 400.00				
TOTAL	OF 21, 22 and 23 =			900.00		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.						
Total Sheets Extra S	E Company	dditional 50 or fraction to a whole number)	RATE			
- 100 =	/50 =		x \$250	\$ 0.00	i	
Surcharge of \$130.00 for after the date of commendate	furnishing any of the search cement of the national stage	\$				
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$		
Total claims	17 - 20 =	0	x \$50	\$ 0.00		
Independent claims	4 -3=	1	× \$200	\$ 200.00		
MULTIPLE DEPENDENT	CLAIM(S) (if applicable)		+ \$360	\$ 0.00		
TOTAL OF ABOVE CALCULATIONS =				\$ 200.00		
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.						
				\$ 1,100.00		
Processing fee of \$130.00 claimed priority date (37 C	o for furnishing the English traces (ii)	anslation later than 30 mont	ns from the earliest +	\$		
TOTAL NATIONAL FEE =			\$ 1,100.00			
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$ 40.00		
TOTAL FEES ENCLOSED =				\$ 1,140.00		
				Amount to be refunded:	\$	
				Amount to be charged	\$	

IAP12 Rec'd PCT/PTO 1 9 MAY 2006

10/580011

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

а. 🔲	A check in the amount of \$ to cover the above fees is enclosed.					
b. X	Please charge my Deposit Account No $08-3255$ in the amount of \$1,140.00 to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. X	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08–3255</u> . A duplicate copy of this sheet is enclosed.					
d. 🗀	Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.						
SEND A	LL CORRESPONDENCE TO: SIGNATURE Marcelo K. Sarkis NAME 37,015 REGISTRATION NUMBER					



Ivor M. Hughes

Barrister & Solicitor

Patent & Trade Mark Agents Canada, United States IAP12 Rec'd PCT/PTO 1 9 MAY 2006

Neil H. Hughes, P.Eng. Marcelo K. Sarkis, P.Eng. Wm. Kitt Sinden Samuel T. Tekie, P.Eng. Francis Ng-Cheng-Hin



Via Courier

The Commissioner of Patents
United States Patent and Trademark Office
Customer Service Window, Mail Stop PCT
Randolph Building
401 Dulany Street
Alexandria, VA 22314
U.S.A.

Dear Sir/Madam:

Re: National Phase Entry in United States

of Tim Fat Tam, Michael Spino, Wanren Li, Yingsheng Wang, Yanqing

€....

Zhao and Birenkumar Hasmukhbhai Shah

for Cycloalkyl Derivatives of 3-Hydroxy-4-Pyridinones

based on International Application No. PCT/CA2004/001986

International Filing Date: November 18, 2004

Priority Date: November 20, 2003

Due Date: May 20, 2006

Please find enclosed herewith the following documentation for filing with the Commissioner in connection with the National Phase entry in the United States of International Application No. PCT/CA2004/001986 under 35 U.S.C. 371:

- 1. Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) concerning a submission under 35 U.S.C. 371 (Form PTO-1390).
- 2. International Publication No. WO 2005/049609 dated June 2, 2005 (*Item 5 of Form PTO-1390*).
- 3. Notification of Transmittal attaching International Search Report and Written Opinion of the International Searching Authority, dated March 14, 2005.

IAP12 Rec'd PCT/PTO 19 MAY 2006



- 2 -

- 4. Declaration of the inventors (Tim Fat Tam, Michael Spino, Wanren Li, Yingsheng Wang, Yanqing Zhao and Birenkumar Hasmukhbhai Shah) (*Item 9 of Form PTO-1390*).
- 5. Notarial copy of Assignment (from Tim Fat Tam, Michael Spino, Wanren Li, Yingsheng Wang, Yanqing Zhao and Birenkumar Hasmukhbhai Shah to Apotex Inc.) and Recordation Form Cover Sheet, Form PTO-1595 (*Item 12 of Form PTO-1390*).
- 6. Powers of Attorney (*Item 16 of Form PTO-1390*) for Bernard C. Sherman, as Chairman & C.E.O. of Apotex Inc., and for each of Tim Fat Tam, Michael Spino, Wanren Li, Yingsheng Wang, Yanqing Zhao, and Birenkumar Hasmukhbhai Shah, as inventors.

The Commissioner is hereby authorized to access our Deposit Account 08-3255 to obtain the amount of U.S. \$1,140.00, comprising of the following:

Description		Fee
Basic filing fee	\$	300.00
Examination fee		200.00
Search fee		400.00
0 total claims over and above the 20 allowed per application		0.00
1 independent claim over and above the 3 allowed per application		200.00
Multiple dependent claim fee		0.00
Size fee for each additional 50 sheets that exceeds 100 sheets		0.00
Recording an Assignment	_	40.00
Total:	\$ 1	,140.00

If there is any discrepancy in the required fees set out above, the Commissioner is authorized to adjust the amount accordingly and advise Applicant's agent.



In addition, please find enclosed a stamped, self-addressed verification card which we request you kindly stamp received and return to this office at the earliest opportunity.

We thank the Commissioner for his cooperation in this regard and look forward to receipt of the filing certificate in this matter.

Respectfully submitted,

Marcelo K. Sarkis

Registration No. 37,015

Agent for Applicant

WKS/jf

Enclosures